AFDO EDUCATIONAL CONFERENCE

Reuse of Single-Use Devices (SUDs)

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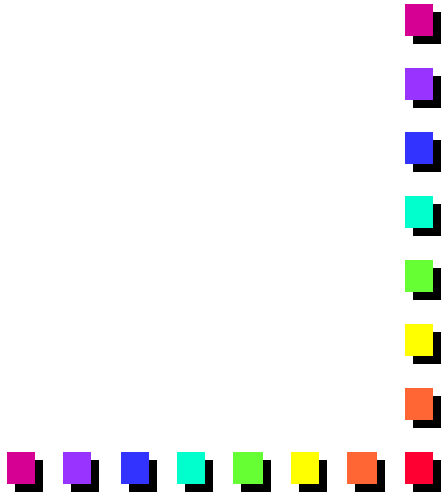
FDA's Position Historically

- Reprocessing in Hospitals/ Clinics (Compliance Policy Guide 300.500)
- Any Person Reprocessing a SUD Is a "Manufacturer"
- Premarket Submissions Have Not Been Requested
- Enforcement Discretion for Hospital Reprocessing

FDA's Position Historically (continued)

- Requirements of 3rd Party Reprocessing Firms:
  - Device Registration/ listing
  - Good Manufacturing Practice (GMP) Inspection
  - Medical Device Reporting
  - General Labeling Requirements
- Reuse Policy Documents & Correspondence: www.fda.gov/ cdrh/ reuse



FDA's Recent Activities

- Active in Conferences/ Meetings
- Reviewed Published Literature
- Conducted Inspections of 3rd Party Reprocessors
- Reviewed/ Analyzed MDR Data

FDA's Recent Activities
(continued)

- Conducted In Vitro Research - biopsy forceps, PTCA and EP Catheters, sutures, etc.
- Published Proposed Reuse Strategy - November, 1999
- Open Public Meeting - December, 1999

FDA's Developing Position

- Intend to Increase Regulatory Oversight
- Plan to Hold Hospitals and Third-Party Reprocessors to Same Requirements
- Two Draft Guidance Documents published February 2000 (http://www.fda.gov/cdrh/reuse):
  - Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals
  - Reprocessing and Reuse of Single-Use Devices; Review Prioritization Scheme

Overview of Guidance Documents

- Applicable to Third-Party Reprocessors and Hospital Reprocessors of SUDs
- Not Applicable to Permanently Implantable Pacemakers, Opened but Unused Devices, Healthcare Facilities That Are Not Hospitals
- Provides List of Frequently Reprocessed Devices, Flowchart, and Tables Identifying Risk Category

Draft Enforcement Priorities Guidance

- Premarket Submissions Based on Risk of Device
- Proposed Timeframes for Premarket Submissions From Date of Guidance Document Finalization:
  - High Risk 6 months
  - Moderate Risk 12 months
  - Low Risk 18 months

Draft Enforcement Priorities Guidance (continued)

- Regulatory Requirements Currently Enforced for Third-Party Reprocessors:
  - Registration and Listing
  - Medical Device Reporting
  - Tracking
  - Corrections and Removals
  - Quality systems Regulation
  - Labeling
- Hospital Must Comply With These Requirements 6 Months After Enforcement Guidance Finalized

Enforcement Timeframes Do Not Preclude FDA From Taking Immediate Action Against an Unsafe Device

Draft Review Prioritization Scheme (RPS)

- Developed as Tool to Establish Categories of SUD Risk After Reprocessing
- Includes Flowcharts and a List of Known Reprocessed SUDs Identifying Their Device Classification (Class I, II, III)
- Risk Categories Only Used for Timing of Premarket Submissions
- Identifies Two Types of Risk that May Exist After Reprocessing: Risk of Infection and Risk of Inadequate Performance

Draft RPS
(continued)

- Three Classes of Risk:
  - High
  - Moderate
  - Low

High-Risk SUDs

- 510(k) or PMA Within 6 Months After Issuance of Final FDA Enforcement Guidance.
- Submission Must Be of Sufficient Quality So That FDA Can Perform Substantive Review
- Reprocessor Must Receive SE or Approval to Market Device Within 6 Months of Filing Deadline

Moderate-Risk SUDs

- Must Submit 510(k) or PMA Within 12 Months of Issuance of Final Enforcement Guidance
- Submission Must Be of Sufficient Quality So That FDA Can Perform Substantive Review
- Reprocessor Must Receive SE or Approval to Market Device Within 6 Months of Filing Date

Low-Risk Devices

- 510(k) or PMA Submitted Within 18 Months of Issuance of Final Enforcement Guidance
- 510(k) or PMA Must Be of Sufficient Quality So That FDA Can Perform Substantive Review
- Reprocessor Must Receive SE or Approval to Market Device Within 6 Months of Filing Date

Classification System

- The Basis for Determining the Process for Marketing a Medical Device in the United States
- The Classes Are:
  - Class I: General Controls
  - Class II: General Controls and Special Controls
  - Class III: General Controls, Special Controls, and Premarket Approval

Class I

- Subject to Least Regulatory Control
- Present Minimal Potential for Harm to the User
- Simpler in Design Than Class II or III Devices

Class III - Premarket Approval

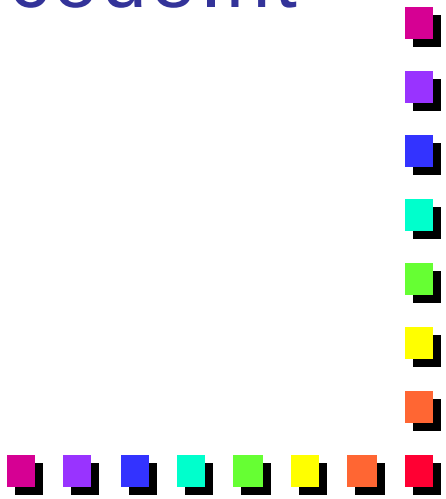
- The Most Stringent Regulatory Category for Medical Devices
- Devices for Which Insufficient Information Exists to Assure Safety and Effectiveness Solely Through General or Special Controls

Device Category, Class and Risk

Medical Specialty/Service	Device	Class (I, II, III)	Risk Category
Cardiovascular	electrophysiology recording catheter	II	high
	percutaneous transluminal angioplasty (PTA) catheter	II	high
Gastroenterology/ Urology	extraction balloons/baskets	II	high
	electric biopsy forceps	II	high
	non-electric biopsy forceps	I	high
Orthopedics	carpal tunnel blade	I	moderate
Dental	braces, plastic	II	high
	braces, metal	I	high
	burr	I	moderate

How To Determine the Regulatory Class of a Medical Device

- Title 21 Code of Federal Regulations (CFR) Parts 862-892.
- Product Code Classification Database (http://www.fda.gov/cdrh/procode.html)



Percentage of Devices in Each Class

- Class I - 46%
- Class II - 47%
- Class III - 7%

Comments to FDA Documents

- Timeframes too Short for Hospitals
- Use the Existing Medical Device Classification System
- Make Worksheets Available
- Modify Scheme to Only Have Two Risk Categories
- Some Devices Rated a Higher Risk Than FDA's Evaluation

Comments to FDA Documents
(continued)

- Inconsistencies in the Categorization of Similar Devices
- Visual Inspection of a Reprocessed SUD Shifts the Burden of Determining If a Device Is Safe and Effective to the User
- Establish an Appeals Process
- Third- party Reprocessors Express Need for More Time to Get Premarket Submissions Cleared

Where Is FDA Going From Here?

- Reviewing All Comments to Proposed Guidances; Plan to Finalize in July 2000
- Considering Options for Use of Risk Prioritization Scheme
- Evaluating Partnership Possibilities With JCAHO; Others May Be Considered Also
- Initiating Extensive Outreach Activities for Hospitals

Where Is FDA Going From Here? (continued)

- Requesting Additional Resources for Implementation
- Encouraging the Development of Standards
- Plan to Continue Laboratory Research
- Other Types of Reprocessors May Be Considered Later for Regulatory Oversight